#### Section 7. Visit Checklists

This section contains examples of checklists detailing the protocol-specified procedures that must be completed at MTN-016 study visits. The checklists also specify the data collection forms that must be completed at each visit. Detailed procedural guidance for performing clinical and laboratory procedures is provided in Sections 10 and 12, respectively. Detailed forms completion instructions are provided in Section 13.

#### 7.1 Use of Checklists

The visit checklists included in this section are designed to guide site staff in proper study procedures as well as to serve as source documentation of procedures performed at study visits. Note, however, that checklists alone may not be sufficient for documenting all procedures. For example, chart notes may be required to:

- Explain why procedures in addition to those listed on a checklist were performed
- Explain why procedures listed on a checklist were not performed
- Document procedures performed at interim visits
- Document the content of counseling sessions and/or other in-depth discussions with participants

See Section 3 for detailed information on source documentation requirements. Tips for completing visit checklists in accordance with these requirements are as follows:

- Enter the participant identification number (PTID) and visit date in the top section of each page of the checklist. If information is written on the front and back of the checklist, enter the PTID and visit date on both sides.
- Enter your initials beside only the procedures that you perform. Do not enter your initials beside procedures performed by other staff members. If other staff members are not available to initial checklist items themselves, enter, initial, and date a note on the checklist documenting who completed the procedure, e.g., "done by {name}" or "done by lab staff."
- If all procedures listed on a checklist are performed on the date entered in the top section of the form, the date need not be entered beside each item. If procedures listed on a checklist are performed on multiple dates, enter the date upon which each procedure is performed beside each item.
- If a procedure listed on the checklist is not performed, enter "ND" for "not done" or "N/A" for "not applicable" beside the item and record the reason why on the checklist (if not self-explanatory); initial and date this entry.

#### 7.2 Sequence of Procedures

The sequence of procedures presented on the visit checklists is a suggested ordering. In consultation with FHI 360, site staff may modify the checklists included in this section to maximize the efficiency of site-specific study operations. Site staff may alter the sequence of procedures to suit local staffing and logistical requirements, with the following exceptions:

- Informed consent for screening and enrollment must be obtained before any study procedures are performed.
- Informed consent for the collection of infant HIV testing must be obtained before any samples are drawn.

NOTE: Checklists in this section are provided as guidelines for the sites. The site can choose to modify these checklists or create their own checklist. Modified checklists should be reviewed by FHI 360 prior to implementation.

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PTID:	Visit	Visit Code: 1.0		
PIID:	Date:	visit Code: 1.0		
	Date			
Initials	Procedures			
IIIIIIII	Confirm participant identity. Cross-check with the MTN-016 Participant Name-			
	PTID Link Log to determine whether a MTN-016 Participant ID number has			
	previously been assigned to the participant.			
	No MTN-016 PTID previously assigned			
	MTN-PTID previously assigned			
	⇒ If this is a subsequent pregnancy, STOP. Complete the Subsequent Pregnancy			
	Visit Checklist.			
	r was construct.			
	Determine participant eligibility based on information available. To be eligible,			
	participant must meet both of the following criteria:			
		Participant has had a known confirmed pregnancy during participation in		
	an eligible parent protocol			
	<ul> <li>Participant is either still pregnant, or the pr</li> </ul>	egnancy outcome occurred less		
	than one year ago	_		
	⇒ If participant is determined to be ineligible, ST	OP. Db not fax any forms to		
	SCHARP.			
	3. Administer and obtain screening and enrollment informed consent with participant			
	according to site SOPs. [For sites using a single maternal/infant consent, both woman			
	and infant consent are done at this time.] Complete Informed Consent Coversheet.			
	⇒ If the participant does not consent to screening and enrollment, STOP. Do not			
	fax any forms to SCHARP.			
	4. Assistant and ACTAL CLE DETERMINE Assistant assistant as a first clear and a second control of the ACTAL CLEAR ASSISTANT AS			
	4. Assign an MTN-016 PTID by completing a new row in the MTN-016 Name-PTID Link Log.			
	Obtain or update locator information     If modical records will be requested from other clinical sites, obtain any necessary.			
	<ol> <li>If medical records will be requested from other clinical sites, obtain any necessary signed local record releases.</li> </ol>			
	7. Complete the Woman Enrollment form.			
	8. Complete the Woman Demographics form.			
	9. Complete the Parent Protocol Participation form.			
	Complete the Farent Protocol Farticipation form.     Complete the Genetic Screening History form.			
	11. Obtain/update medical history. Document on Won	an Medical History Log		
	(non-DataFax) or approved alternative source per site S			
	12. Document all medications taken during the pregnan			
	Concomitant Medications Log.			
	13. Obtain pregnancy history and complete the Pregna	ncy Report and History form.		
	Note that MTN-016 pregnancy history form is more de			
	14. If available, review and document ultrasound exam			
	Ultrasound Results form.	*		
	15. If woman has experienced pregnancy outcome at th	e time of enrollment, complete		
	all procedures identified on the Pregnancy Outcome f			
	16. Provide coaching or counseling on any issues as inc			
	visit			
	17. Provide site contact information and remind partici	pant to contact site staff if		
	needed prior to next scheduled visit.			
	18. Schedule next visit.			
	19. Provide reimbursement.			

## Screening and Enrollment Visit: Woman Page 2 of 2

PTID:	Visit Date:	Visit Code: 1.0	
Initials	Procedure	<del></del>	
	<ol><li>Review and fax all required DataFax forms</li></ol>	to SCHARP DataFax:	
	□ Woman Enrollment		
	□ Woman Demographics		
	☐ Parent Protocol Participation		
	☐ Genetic Screening History		
	☐ Ultrasound Results		
	☐ Pregnancy Report and History		
	☐ Woman Concomitant Medications Log		
	As Needed:		
	☐ Pregnancy Outcome		
	21. Place all study visit checklists, chart notes, case report forms, and other study		
	documents identified with a PTID only in an MTN-016 participant notebook assigned		
	to the participant.		

### **Quarterly Visit: Woman**

# Page 1 of 1

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PTID:		Visit Date:	Visit Code:
Initials			
	<ol> <li>Complete participant registration, confirm participant's identity, verify PTID.</li> </ol>		
	2. Review/update locator information		
	3. Update medical history and document on Woman Medical History Log (non-		
	DataFax) or approved alternative source per site SOPs.		
	4. Update the Woman Concomitant Medications Log. Document review with a		
	signed and dated note on each document reviewed. Initial and date updated entries.		
	Review genetic screening history and update the Genetic Screening History form accordingly.		
	6. Update pregnancy h	istory, including pregnancy-relat	ted morbidities such as
	hypertensive disorders	of pregnancy, antenatal hemorrh	nage, and abnormal
	placentation. Update th	ne Pregnancy Report and Histo	ory form accordingly.
	7. Perform or schedu	le ultrasound if results of an u	iltrasound from this
	pregnancy are not available. Complete the Ultrasound Results form.		
	8. If woman has experienced a pregnancy outcome at the time of visit, obtain medical		
	records, and complete all procedures identified for the Pregnancy Outcome form.		
	9. Inquire about social harms. If a social harm is reported, complete the Social Harms		
	Assessment Log form.		
	10. Complete the Woman Follow-up Visit form.		
	11. Provide coaching or counseling on any issues as indicated by content of		
	participant visit.		
	<ol><li>Remind participant to contact site staff if needed prior to next scheduled visit.</li></ol>		
	<ol><li>Schedule next visit and/or confirm estimated date of delivery.</li></ol>		of delivery.
	14. Provide reimburser		
		taFax forms to SCHARP DataF	ax:
	□ Woman Fo	-	
	☐ Ultrasound Results		
	☐ Pregnancy Report and History (only refax updated pages)		
	☐ Genetic Screening History (only re-fax updated pages)		
	☐ Woman Concomitant Medications Log (only refax any new or updated		
	pages) As Needed:		
		ms Assessment Log	
	☐ Pregnancy		
		t checklists, chart notes, case rep	out forms and other study
		vith a PTID only in an MTN-016	
	to the participant.	in a 1 2115 only in an infin-ore	participant notcoock assigned
	To me participant.		

#### **Interim Visit: Woman**

### Page 1 of 1

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PTID:	Visit Date:	Visit Code:			
1 20 1					
Initials	Procedures  1. Complete participant registration, confirm participant's identity, verify PTID.				
		rm participant's identity, verify PTID.			
Review/update locator information.     General to the Wesser Interior Visit form					
	Complete the Woman Interim Visit form.      Update medical history and document on Woman Medical History Log form      Details of appropriate appropriate SOPs.      Details of the Propriate SOPs.				
	(non-DataFax) or approved alternative source per site SOPs.				
	1	5. Assess concomitant medications, if indicated. Review/update the Woman  Concomitant Medications Log. Document review with a signed and dated note on			
	each document reviewed	ant review with a signed and dated note on			
	Carrie de Carrie	narm is reported, complete the Social Harms			
	Assessment Log form.	in in repercos, comprete the social riving			
	7. If reason for visit is to:				
	Report pregnancy outcome, complete all procedures identified on the				
	Pregnancy Outcome Form.				
	<ul> <li>Perform ultrasound assessmen</li> </ul>	it, complete the Ultrasound Results form			
Provide coaching or counseling on any issues as indicated by content					
visit					
	visit				
	visit  9. Remind participant to contact site staff i	if needed prior to next scheduled visit.			
	visit  9. Remind participant to contact site staff i  10. Fax the required DataFax forms to SCI	if needed prior to next scheduled visit.			
	visit  9. Remind participant to contact site staff:  10. Fax the required DataFax forms to SCI  Woman Interim Visit	if needed prior to next scheduled visit.			
	visit  9. Remind participant to contact site staff:  10. Fax the required DataFax forms to SCI  Woman Interim Visit As Needed:	if needed prior to next scheduled visit.			
	visit  9. Remind participant to contact site staff i  10. Fax the required DataFax forms to SCI  Woman Interim Visit  As Needed:  Pregnancy Outcome	if needed prior to next scheduled visit.			
	visit  9. Remind participant to contact site staff i  10. Fax the required DataFax forms to SCI  Woman Interim Visit  As Needed:  Pregnancy Outcome  Ultrasound Results	if needed prior to next scheduled visit. HARP DataFax:			
	visit  9. Remind participant to contact site staff in the	if needed prior to next scheduled visit. HARP DataFax:			
	visit  9. Remind participant to contact site staff in the required DataFax forms to SCI    Woman Interim Visit   As Needed:  Pregnancy Outcome    Ultrasound Results    Woman Concomitant Medium    Woman Termination	if needed prior to next scheduled visit.  HARP DataFax:  dications Log			
	visit  9. Remind participant to contact site staff in the	if needed prior to next scheduled visit.  HARP DataFax:  dications Log  entory			
	visit  9. Remind participant to contact site staff in the required DataFax forms to SCI    Woman Interim Visit   As Needed:  Pregnancy Outcome    Ultrasound Results    Woman Concomitant Medium    Woman Termination	if needed prior to next scheduled visit.  HARP DataFax:  dications Log  entory			
	visit  9. Remind participant to contact site staff i  10. Fax the required DataFax forms to SCI  Woman Interim Visit  As Needed:  Pregnancy Outcome  Ultrasound Results  Woman Concomitant Med  Woman Termination  Woman End of Study Investigation  Social Harms Assessment  11. Place all study visit checklists, chart no	if needed prior to next scheduled visit. HARP DataFax: dications Log entory Log otes, case report forms, and other study			
	visit  9. Remind participant to contact site staff i  10. Fax the required DataFax forms to SCI  Woman Interim Visit  As Needed:  Pregnancy Outcome  Ultrasound Results  Woman Concomitant Med  Woman Termination  Woman End of Study Investigation  Social Harms Assessment  11. Place all study visit checklists, chart no	if needed prior to next scheduled visit.  HARP DataFax:  dications Log  entory Log			

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	PTID:	Visit	Visit Code:	1.0	
١	PIID:	Date:	visit code:	1.0	
ŀ					
ŀ	Initials	Procedures			
ł			Confirm participant identity. Cross-check with the MTN-016 Participant Name-		
١		PTID Link Log to confirm MTN-016 that Participant ID number has previously been			
١		assigned to the participant.			
١		☐ MTN-PTID previously assigned			
١		□ No MTN-016 PTID previously assigned			
١		⇒ If this is not a subsequent pregnancy, STOP. Complete the Woman Screening			
١		& Enrollment Visit Checklist.			
l					
١		<ol> <li>Determine participant eligibility based on information available. To be eligible,</li> </ol>			
١		participant must meet both of the following criteria:			
١			☐ Participant has had a known confirmed pregnancy during participation in an		
١		eligible parent protocol  Participant is either still pregnant, or the pregnancy outcome occurred less than			
١		one year ago	icy outcome occur	eu iess man	
١			OP Complete item	2 of the	
1			⇒ If participant is determined to be ineligible, STOP. Complete item 2 of the Woman Enrollment form. Do not fax any forms to SCHARP.		
1					
ı		3. Administer and obtain screening and enrollment informed consent with participant			
١		according to site SOPs. [For sites using a single maternal/infant consent, both woman			
1		and infant consent are done at this time.] Complete Informed Consent Coversheet.			
١		⇒ If the participant does not consent to screening and enrollment, STOP. Do no		OP. Do not	
		fax any forms to SCHARP.			
ł		4. Update locator information.			
Ì		5. If medical records will be requested from other clinical sites, obtain any necessary			
		local record releases.			
ļ		6. Complete the Woman Subsequent Consent form.			
-		7. Obtain genetic screening history and complete the Genetic Screening History			
1		form.			
-		⇒ Note that father may be different or new information may be available from			
		previous pregnancy.			
ŀ		8. Obtain/update medical history. Document on Woma	n Medical History	Log form	
		(non-DataFax) or approved alternative source per site SOPs.			
Ì		9. Assess concomitant medications. Review/update the Woman Concomitant			
		Medications Log form(s). Document review with a signed and dated note on each			
		document reviewed. Initial and date updated entries.			
		<ol> <li>Obtain pregnancy history and complete the Pregnance</li> </ol>			
		11. If available, review and document ultrasound exam	results and complet	te the	
		Ultrasound Results form.			
		12. If woman has experienced the subsequent pregnancy			
		obtain medical records, and complete all procedures ide	entified for the Preg	nancy	
-		Outcome form.  13. Inquire about social harms. If a social harm is reported to the social harms of the social harms is reported to the social harms.	rtad complete the S	ocial	
		Harms Assessment Log form.	rea, complete tile 3	ociai	
ŀ		14. Provide coaching or counseling on any issues as ind	licated by content o	f participant	
		visit.		- paracipant	
ŀ		15. Provide site contact information and remind particip	ant to contact site	staff if	
		needed prior to next scheduled visit.			
L		server prove at Milit Shithwall Table.			

## Subsequent Pregnancy: Woman

## Page 2 of 2

	Visit Date:		Visit Code: 1.0
		dures	
<ol><li>Schedule next visit</li></ol>	t, if applicable		
17. Provide reimburser	ment.		
18. Review and fax all required DataFax forms to SCHARP DataFax:			
☐ Woman Subsequent Consent			
☐ Pregnancy Report and History			
☐ Genetic Screening History			
☐ Woman Concomitant Medications Log (only refax new or updated pages)			
☐ Ultrasound Results			
As Needed:			
□ Pregnancy Outcome			
19. Place all study visit checklists, chart notes, case report forms, and other study			
documents identified with a PTID only in an MTN-016 participant notebook assigned to the participant.			
	17. Provide reimburset  18. Review and fax all  Woman Si Pregnancy Genetic Si Woman C Ultrasoum As Needed: Pregnancy  19. Place all study visit documents identified to	Proce  16. Schedule next visit, if applicable  17. Provide reimbursement.  18. Review and fax all required DataFax fo  Woman Subsequent Consent  Pregnancy Report and History Genetic Screening History  Woman Concomitant Medicati Ultrasound Results  As Needed: Pregnancy Outcome  19. Place all study visit checklists, chart no documents identified with a PTID only in a	Procedures  16. Schedule next visit, if applicable  17. Provide reimbursement.  18. Review and fax all required DataFax forms to SCH  Woman Subsequent Consent  Pregnancy Report and History Genetic Screening History Woman Concomitant Medications Log (or Ultrasound Results  As Needed: Pregnancy Outcome  19. Place all study visit checklists, chart notes, case rep

PTID:		Visit Date:	Visit Code: 1.0
		Date.	
le itie le	s Procedures		
Initials	Confirm whether or not infant consent has already been obtained.		
	☐ Infant consent already obtained.		
	☐ Infant consent aready obtained.		
	☐ Explain the informed consent process to the infant's parent/guardian.		
	Administer and obtain screening and enrollment informed consent for the		
	infant according to site SOPs.		
	Document process in chart notes and/or the Informed Consent Coversheet		
	⇒ If the infant's parent/guardian does not consent to screening and enrollment,		
	STOP. Do not fax any forms to SCHARP.		
	2. Confirm eligibility	assign infant PTID, and complete	the Pregnancy Outcome
	form, item 9.	assign miant F11D, and complete	e me i reguancy Outcome
	3. Review/update local	tor information.	
		or the infant will be requested fro	m other clinical sites, obtain
	any necessary local rec		,
	5. Complete Infant Er		
	6. Review/update infar	nt medical/birth history and comp	olete the Infant Medical
	History Log form (non-DataFax).		
	7. Document all medications since birth on the Infant Concomitant Medication I		
	and all vaccinations since birth on the Infant Vaccination Log		
	Conduct and record infant physical exam as per protocol:    Complete the Infant Ministry of the Protocol		
	☐ Complete the Infant Visit form.		
	<ul> <li>□ Complete the Infant Physical Exam form.</li> <li>□ If there are any suspected or confirmed abnormalities, complete the Major</li> </ul>		
		Eligibility Assessment Workshe	
	AND	the Major Malformation Asses	sment Form (section 10.7.2)
	☐ Confirm that consent has been granted and collect photo images (section		
	10.7.3). If photographs are taken, complete the Infant Visit form, item:		
	9. As necessary, perform infant HIV testing and complete Infant HIV Test Results		
	and MTN-016 (Non-DataFax) LDMS Specimen Tracking Sheet		
	10. Inquire about social harms. If a social harm is reported, complete the Social		
	Harms Assessment L	og form.	
	11. Provide coaching or counseling on any issues as indicated by content of visit		
	12. Remind participant to contact site staff if needed prior to next scheduled visit.		
	13. Schedule next visit.		
	<ol><li>Provide reimburser</li></ol>		
		ataFax forms to SCHARP DataF	ax:
	☐ Infant Enr		
	☐ Infant Vis		
	☐ Infant Phy		
		ncomitant Medications Log	
	As Needed:	regnancy Outcome Form	
	As Needed:	cination I or	
	☐ Infant Vac		
		t checklists, chart notes, case rep	ort forms, and other study
	documents identified with a PTID only in an MTN-016 participant notebook assigned to the participant.		

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	PTID:	Visit Date:	Visit Code:		
I					
	Initials	Procedures			
l		Confirm whether or not infant consent has already been obtained.			
l		☐ Infant consent already obtained.			
l		<ul> <li>Complete participant registration, confirm participant's identity, verify</li> </ul>			
l		PTID.  Infant consent not yet obtained.			
I		Explain the informed consent process to the infant's parent/guardian.			
l		Administer and obtain screening and enrollment informed consent for the			
l		infant according to site SOPs.			
l		<ul> <li>Document process in chart notes and/or the</li> </ul>	Informed Consent Coversheet		
I		<ul> <li>Confirm eligibility.</li> </ul>			
١		<ul> <li>Confirm and assign infant PTID, complete.</li> </ul>			
١		Outcome form, item 9 and complete Infan			
١		⇒ If the infant's parent/guardian does not consent to screening and enrollment,			
ļ		STOP. Do not fax any forms to SCHARP.			
ļ		Review/update locator information.			
l		3. Update medical history and document on Infant Medical History Log (non-			
ŀ		DataFax).			
l		4. Review/update the Infant Concomitant Medications Log and the Infant Vaccination Log (if applicable). Document review with a signed and dated note on			
l		each document reviewed. Initial and date updated entries.			
ŀ		Conduct and record infant physical exam as per protocol.			
l		Complete the Infant Visit form.			
I		☐ Complete the Infant Physical Exam form.			
I		☐ If there are any suspected or confirmed abnorm	alities, complete the Major		
I		Malformation Eligibility Assessment Workshee	et (section 10.7.1). If directed,		
		☐ Complete the Major Malformation Assess	sment Form (section 10.7.2)		
I		AND			
		☐ Confirm that consent has been granted and			
ŀ		10.7.3). If photographs are taken, complete the Infant Visit form, item 5.			
ı		6. As necessary, follow-up on or perform infant HIV te			
ŀ		Test Results and MTN-016 (Non-DataFax) LDMS Spe			
		<ol> <li>Inquire about social harms. If a social harm is report Assessment Log form.</li> </ol>	eu, complete the social Harms		
ŀ		Provide coaching or counseling on any issues as indi	cated by content of infant visit		
ŀ		Months 1 & 6: Remind participant to contact site state			
		scheduled visit.	2 2 200000 prior to man		
ŀ		10. Months 1 & 6: Schedule next visit			
ŀ		11: Month 12: Complete the Infant Termination and I	nfant End of Study		
		Inventory forms.			
ŀ		12. Provide reimbursement			
и					

# Month 1, 6, and 12: Infant

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PTID:	Visit Date:	Visit Code:
Initials	Procedures	
	13. Fax the required DataFax forms to SCHARP DataFax:    Infant Visit   Infant Physical Exam   As Needed:   Infant Enrollment   Updated Pregnancy Outcome Form   Infant Concomitant Medications Log (refax any new or updated pages)   Infant Vaccination Log   Infant HIV Test Results   Social Harms Assessment Log   At Month 12 only:   Infant Termination   Infant End of Study Inventory	
	14. Place all study visit checklists, chart notes, case report forms, and other study documents identified with a PTID only in an MTN-016 participant notebook assigned to the participant.	

Interim Visit: Infant

## Page 1 of 2

PTID:	Visit Date:	Visit Code:	
	Date.		
Initials	Procedures		
·······	Confirm whether or not infant consent has already been obtained.		
	☐ Infant consent already obtained.		
	□ Complete participant registration, confirm participant's identity, verify		
	PTID.		
	☐ Infant consent not yet obtained.		
	<ul> <li>Explain the informed consent process to the infant's parent/guardian.</li> </ul>		
	<ul> <li>Administer and obtain screening and enrollment informed consent for the</li> </ul>		
	infant according to site SOPs.		
	Document process in chart notes and/or the	e Informed Consent Coversheet	
	Confirm eligibility	handata tha Danamana	
	Confirm and assign infant PTID, complete		
	Outcome form, item 9, and Infant Enrolls		
	⇒ If the infant's parent/guardian does not consent to screening and enrollment,		
	STOP. Do not fax any forms to SCHARP  2. Review/update locator information.		
	3. Complete the Infant Interim Visit form.		
	4. Update medical history and update the Infant Medic	al History Log	
	5. Assess concomitant medications, if indicated. Revie		
	Concomitant Medications Log and the Infant Vaccin		
	with a signed and dated note on each document reviews		
	6. Inquire about social harms. If a social harm is reported, complete the Social Harms		
	Assessment Log form.		
	7. If reason for visit is to follow up on or perform infant HIV testing, complete Infant		
	HIV Test Results and MTN-016 (Non-DataFax) LDM	S Specimen Tracking Sheet	
	8. If indicated, conduct and record infant physical exam	(note: if infant is enrolling	
	during this interim visit, full physical exam including w		
	circumference, and abdominal circumference (prior to 1	l month of age) must be	
	completed):		
	<ul> <li>□ Complete the Infant Physical Exam form.</li> <li>□ If there are any suspected or confirmed abnorm</li> </ul>	alities, complete the Major	
	Malformation Eligibility Assessment Workshee		
	☐ Complete the Major Malformation Assess		
	AND		
	☐ Confirm that consent has been granted and	collect photo images (section	
	10.7.3). If photographs are taken, complete		
	<ol><li>Provide coaching or counseling on any issues as indi-</li></ol>	cated by content of visit	
	<ol><li>Remind participant to contact site staff if needed pri</li></ol>	ior to next scheduled visit.	

#### Interim Visit: Infant Page 2 of 2

PTID:	Visit Date:	Visit Code:		
Initials	Procedures			
	<ol> <li>Fax the required DataFax forms to SCHARP DataF</li> </ol>	ax:		
	☐ Infant Interim Visit			
	As Needed:			
	☐ Infant Enrollment			
	Updated Pregnancy Outcome Form	□ Updated Pregnancy Outcome Form		
	<ul> <li>Infant Concomitant Medications Log</li> </ul>	☐ Infant Concomitant Medications Log		
	<ul> <li>Infant Vaccination Log</li> </ul>			
	Infant HIV Test Results	Infant HIV Test Results		
	☐ Infant Physical Exam	Infant Physical Exam		
	☐ Infant Visit	☐ Infant Visit		
	☐ Infant Termination			
	☐ Infant End of Study Inventory			
	☐ Social Harms Assessment Log			
	12. Place all study visit checklists, chart notes, case rep	ort forms, and other study		
	documents identified with a PTID only in an MTN-016	participant notebook assigned		
	to the participant			